

REMARKS

No amendments have been made to the claims; they are reproduced here solely for the convenience of the Office. As a preamble, applicants wish to express their appreciation for the clarity of the Office action and for the withdrawal of a number of rejections. The sole rejection remaining is under 35 U.S.C. § 112, first paragraph. The basis for the Office's argument is that claims of the scope of claims 19 and 24-26 are new matter and not supported by the specification, as Example 4 is not considered generic.

Based on the rationale provided by the Office, applicants do not understand why claim 26 is included within this rejection. Claim 26 is limited to *S. erythraea* strain A34, which is exemplified in Example 4, and it depends from claim 24 which is limited to structures 6 and 7 which are directly employed in this example. As applicants understand the rejection, there is no assertion that the work of Example 4 is questioned; rather it is the generalization of this subject matter to which the Office objects. Respectfully, then, it is submitted that at least claim 26 is in a position for allowance.

As to claims 19 and 24-25, it appears the applicants and the Office disagree on the disclosure as described in the example itself. Applicants believe that the introductory paragraph to this example clearly indicates that applicants are testing whether post-translational processing in *S. erythraea* will be effective with regard to "unnatural substrates" – *i.e.*, modified forms of 6-dEB. These "unnatural substrates" are clearly intended to be those resulting from other than the natural starter unit – *i.e.*, those described in the claim as having a substituent other than methyl or ethyl at position 13. This is clear from the description on page 3, lines 3-6. The Office does indeed

recognize this as the subject matter of the disclosure. Therefore, when Example 4 refers to “unnatural substrates” it clearly refers to the modified forms of 6-dEB as set forth in claim 19.

The only reason that the *S. erythraea* mutant A34 is used in this example is that since it is unable to synthesize 6-dEB, but able to process 6-dEB by glycosylating it, use of this strain would eliminate complications in assessing the results that would occur if wildtype were used and 6-dEB were made by the host. It would be more complex to test whether the conversion of the “unnatural” – *i.e.*, modified 6-dEB, had occurred if 6-dEB were also present. Respectfully, it is believed that one of skill in this art would understand, without having this pointed out, that this is the sole reason for using such a mutant – for convenience in testing, not because the mutant is expected to be particularly effective.

With this in mind, it appears that the disagreement between the applicants and the Office resides in the manner in which the description of Example 4 should be interpreted. Applicants believe that the introductory paragraph, which states that the purpose of the experiment is “to determine whether the post-PKS enzymes in the erythromycin biosynthetic pathway might also accept unnatural substrates,” conveys the meaning that, if successful, the results would lead to the conclusion that this is the case. The results were successful, and applicants believe it is unnecessary for the application to have stated that the articulated purpose of the experiment was met in order to retain the generality of the example. Applicants also believe that it should be unnecessary to explain to the skilled artisan that *S. erythraea* mutant A34 is used only for convenience in testing, not because it has any particular post-PK synthesis enzymes that are different from other *S. erythraea* strains.

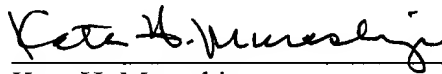
Applicants respectfully request the Office to reconsider its position in light of the foregoing explanation, and pass claims 19 and 24-26 to issue.

If any issues remain that might be resolved by phone, a telephone call to the undersigned would be welcome.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 300622000212.

Respectfully submitted,

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